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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 1 and 2

[Docket No. APHIS-2014-0050]

Petition to Define Alternatives to Procedures That May Cause Pain or Distress and to Establish Standards Regarding Consideration of These Alternatives

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of petition.

SUMMARY: We are notifying the public that the Animal and Plant Health Inspection Service has received a petition requesting that we amend the Animal Welfare Act (AWA) regulations to define the term alternatives, clarify the existing definition of painful procedure, and establish standards governing the consideration of such alternatives at research facilities that are registered under the AWA regulations. We are making this petition available to the public and soliciting comments regarding the petition and any issues raised by the petition that we should take into account as we consider this petition.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0050.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2014-0050, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0050 or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Carol Clarke, Research Program Manager, USDA, APHIS, Animal Care, 4700 River Road Unit 84, Riverdale, MD 20737-1234; (301) 851-3751.

SUPPLEMENTARY INFORMATION:

The Animal Welfare Act (AWA, 7 U.S.C. 2131 et seq.) authorizes the Secretary of Agriculture to promulgate standards and other requirements governing research facilities. The Secretary has delegated the responsibility for enforcing the AWA to the Administrator of the Animal and Plant Health Inspection Service (APHIS). Within APHIS, the responsibility for administering the AWA has been delegated to the Deputy Administrator for Animal Care.

Regulations and standards promulgated under the AWA are contained in Title 9 of the Code of Federal Regulations, parts 1, 2, and 3 (referred to collectively below as the AWA regulations). Part 1 contains definitions of terms used within parts 2 and 3. Part 2 contains licensing and registration regulations, regulations specific to research facilities, and regulations governing veterinary care, animal identification, recordkeeping, access for inspection,

confiscation of animals, and handling, among other requirements. Within part 2, subpart C contains the regulations specific to research facilities.

Among other requirements, research facilities, other than Federal research facilities, must register with APHIS and appoint an Institutional Animal Care and Use Committee (IACUC). The IACUC, which must be composed of a chairperson and at least two other members, is required to perform certain functions in order to ensure the facility's compliance with the AWA regulations.

As one of these functions, the IACUC must review proposed activities involving animals that are performed at the facility, as well as significant changes in ongoing activities, in order to determine that the principle investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources used to determine that alternatives were not available.

On October 30, 2013, APHIS received a petition from the Physicians Committee for Responsible Medicine (referred to below as PCRM) requesting that we initiate rulemaking to amend the AWA regulations. Specifically, PCRM asks that we amend part 1 to add a definition of the term alternatives in order to delineate what a primary investigator is required to consider in lieu of a procedure that may cause more than momentary or slight pain or distress to the animals. The petition also asks that we amend the existing definition of painful procedure in order to codify a long-standing APHIS policy that a procedure should be considered to be painful if it may cause more than momentary or slight pain of distress to the animals, even if this pain is subsequently relieved through anesthesia. Finally, the petition asks that we amend part 2 to specify what must occur as part of a consideration of alternatives.

The petition states that the intent of the AWA is to authorize research facilities to undertake procedures likely to produce pain or distress in animals only if no alternatives exist to these procedures, and that the AWA regulations support this interpretation of the AWA itself. The petition suggests, however, that because of ambiguities in the AWA regulations, research facilities have sometimes construed them to mean that cursory deliberation regarding alternatives suffices to meet this regulatory and statutory requirement to consider alternatives. The petition states that, by amending the AWA regulations in the manner that PCRM suggests, we would remove these ambiguities and facilitate regulatory compliance.

We are making this petition available to the public and soliciting comments to help determine what action, if any, to take in response to this request. The petition and any comments submitted are available for review as indicated under ADDRESSES above. We welcome all comments on the issues outlined in the petition. In particular, we invite responses to the following questions:

1. Should APHIS establish regulatory standards for consideration of alternatives to procedures that may cause more than momentary or slight pain or distress to animals?
2. What constitutes an alternative to a procedure that may cause more than momentary or slight pain or distress? If we amend the AWA regulations to define the term alternative, what definition should we use?
3. What constitutes a thorough consideration of alternatives? Does this differ depending on the nature of the research conducted? If so, how?

4. Who should make a determination regarding the thoroughness of a primary investigator's consideration of alternatives: The IACUC for a facility, APHIS, or both parties?
5. If the IACUC and APHIS should jointly make a determination, which responsibilities should fall to APHIS and which to the IACUC in terms of evaluating thoroughness?
6. What documentation should the primary investigator provide to demonstrate that he or she has done a thorough consideration of alternatives?

We encourage the submission of scientific data, studies, or research to support your comments and position. We also invite data on the costs and benefits associated with any recommendations. We will consider all comments and recommendations we receive.

Authority: 7 U.S.C. 2131-2159; 7 CFR 2.22, 2.80, and 371.7.

Done in Washington, DC, this 24th day of March 2015.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.

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